

Revised 5/14/2018 for Ad Hoc – Added PODs for dermal, inhalation, and oral routes and calculated MOEs for workers and gen pop using thes PODs. Changes in RED.

SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard, and/or other structural information. EPA concludes there is moderate concern for human health hazard for the chemical substance.

Based on the hazard determination and available qualitative risk information, EPA concludes that there is risk for the PMN substance.

Human Health Hazard:

- Absorption of the PMN nil all routes. Absorption of the low MW Fractions is poor all routes based on P-chem properties (molecular weight and vapor pressure).
- Based on multiple acrylate groups there is concern for irritation of eyes and skin, developmental toxicity, liver toxicity, and kidney toxicity.
- [REDACTED] was identified as a worst case analog, which has a dermal NOAEL of 1,081 mg/kg (highest dose tested) based on a lifetime study in male mice. [REDACTED] also has an inhalation NOAEC of 225 mg/m³ based on elevated liver enzymes in female mice in a 90-day inhalation study. The NOAEC is also protective of developmental toxicity.
- [REDACTED] was identified as an analog, which has an oral NOAEL of 111 mg/kg (highest dose tested) based on a 90-day drinking water study in rats. This NOAEL is also protective of developmental toxicity.
- Both analogs are negative for genotoxicity in vitro and in vivo studies. [REDACTED] is not considered carcinogenic and [REDACTED] was not carcinogenic to rats via inhalation exposure up to 773 mg/m³.

Human Health Risk:

- Potential risks were identified for workers for irritation of eyes and skin and sensitization via dermal and inhalation exposures based on the presence of multiple acrylate groups. Potential

risks for these hazard endpoints were not quantified due to a lack of dose-response for this hazard. Due to estimated exposures, risks cannot be ruled out. Risks would be mitigated if exposure can be controlled by the use of appropriate PPE, including impervious gloves, eye protection, and a respirator. An APF cannot be specified due to the lack of quantitative data and given the lack of quantitative hazard data, the decrease in risk from using PPE (e.g., a respirator) is not known.

- Risks were not identified for workers for systemic toxicity via dermal exposures based on quantitative hazard data for a component of the new chemical (MOE = 512; benchmark MOE = 100).
- Risks were not identified for workers for systemic toxicity via dermal inhalation exposures based on quantitative hazard data for a component of the new chemical (MOE = 898; benchmark MOE = 100).
- Risks were not identified for the general population for systemic effects via oral exposures based on quantitative hazard data for a component of the new chemical (MOE > 1,000 for adults and susceptible subpopulations; benchmark MOE = 100).
- Risks were not quantified for the general population for systemic effects via inhalation since exposure was below the modeling threshold.
- Risks were not quantified for consumers since consumer use is not expected.

Potentially Useful Information:

- Information on reproductive effects (development of the offspring) and sensitization.

PART A

SAT Date: 02/06/2018

SAT Chair: William Irwin

Health Assessor: Lemuel Russell

QC Reviewer: Louis Scarano, 2/11/18

Structure:

PMN: P-18-0102	Submitter: Allnex USA Inc.				Manu.	Import
Max. PV (KG):		Binding Option Marked:				X
MW:	1315	8.1	% < 500	26.2	% <1000	CASNO
PMN Structure					Prop.	Meas.
						Est.
					MP	
					BP	
					Pres.	at 760 mm Hg
					VP	<0.000001
					S-H2O	Dispersible
					log P	

- CASRN:
- Chemical Category:
 - Acrylate Acryate FGEW
- Chemical Category Health Concerns:
 - Sensitization, Irritation
- Category Testing Strategy:
 -
- PMN Health Rating:
 - 2
- SAT Key Words:
 - Irr- E S; Muta; Onco; Dev; Liver; Kidney
- Absorption:

- Parent molecule: Nil all routes, Low MW Fractions (%<500:8.10 %<1000:26.20) Poor all routes based on P-chem properties.
- **SAT Health Summary:**
 - Acrylate polymers. Based on multiple acrylate groups there is concern for irritation of eyes and skin, sensitization, genotoxicity, developmental toxicity, liver toxicity, kidney toxicity, oncogenicity.
- **Analog Data:** (analog, structure, study summary, POD)
 - Analog: Dermal LD50 > 2000 mg/kg
- **Other Information:** (structural alert or component of interest, basis, etc.)
 - SDS
- **Point of Departure Selected and Basis:**
 - None identified

Exposure Routes of Interest:

- ☒ Inhalation
- ☒ Dermal
- ☒ Ingestion

PART B

Focus Date: 2/15/18

Focus Assessor: J Congleton








QC: Sailesh Surapureddi

USES and EXPOSURES:







- **Uses:** Waterborne polymer binder for inkjet ink or overprint varnish.
- **Worker Exposure:**
 - **Inhalation:** Exposure to Particulate (non volatile) (Class I)
Potential Dose Rate: [REDACTED]
Basis: [REDACTED]
 - **Dermal:** Exposure to Liquid at [REDACTED]
Potential Dose Rate: [REDACTED]
Basis: [REDACTED]
- **General Population Exposure:**
 - **Drinking Water:** ADR as high as [REDACTED]
 - **Fish:** Not calculated
 - **Air/Inhalation:** Below modeling thresholds
- **Consumer Exposure:** Not calculated since consumer use is not expected

RISK CALCULATIONS:

- **Worker Calculations:**
 - Risks were not identified for workers for systemic toxicity via dermal exposures based on quantitative hazard data for a component of the new chemical (MOE = 512; benchmark MOE = 100).

Focus Worker Calculations $MOE = (POD \times Abs\ Rate) / ((PDR \times Abs\ Rate) / BW)$ Acceptable $MOE \geq 100$								
Exposure Scenarios and Values ¹	POD= NOAEL (mg/kg/day)	POD Route Absorp . Adj ²	Potential Dose Rate (mg/day)	Exposure Route Absorp Adj ²	Structural Alert/ Component as % of PMN	Avg BW ³ All Adults, 80 (kg)	Margin of Exposure ⁴ (POD/PMN Dose)	
WORKER RISK								(NOAEL=100)
Highest/Worst Case Doses from Engineering Report								(LOAEL=1000)
Dermal								
¹ Doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day. The EPA/OPPT 2-Hands Dermal Contact with Liquids Model calculates worker dermal exposures to a liquid. Model assumptions are: (1) surface area of contact equals two hands (1,070 cm ²); (2) high-end default value of quantity remaining on skin = 2.1 mg/cm ² (low-end default = 0.7 mg/cm ²); (3) weight fraction of chemical in liquid; (4) 1 contact/worker-day; (5) no use of controls or gloves to reduce exposure; (6) exposure duration = 1 to 4 hours based expectation that worker will, at a minimum, thoroughly wash hands at lunch or end of the day. ² Absorption adjustments for Focus - Assume 100% for POD; For Exposure. If risks, consider adjustments for absorption, etc. ³ USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies, Table 8-1, Recommended Values for Body Weight http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf ⁴ Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment								

- Risks were not identified for workers for systemic toxicity via dermal inhalation exposures based on based on quantitative hazard data for a component of the new chemical (MOE = 898; benchmark MOE = 100).

Worker Risks via Inhalation; HEC in mg/m ³ MOE = Adj HEC / (Adj PDR); Benchmark (acceptable) MOE ≥100							
Exposure Scenarios	HEC ¹ (mg/m ³)	Potential Dose Rate ² (mg/day)	8 hour exposure concentration ³ (mg/m ³)	Exposure Route Absorption Adj ⁴	Structural Alert/ Component as % of PMN	Margin of Exposure (HEC/ PDR)	Inhalation Fold Factor (Benchmark/ MOE) ⁵
WORKER RISK							(NOAEL=100)
Highest/Worst Case Doses from Engineering Report							(LOAEL=1000)
Inhalation (NOEC)							
¹ HEC is the Human Equivalent Concentration adjusted from the animal POD based on exposure duration. Animal NOAEC (225 mg/m ³ was adjusted for experiment frequency and duration of exposure in addition to adjusting resting breathing rates to worker breathing rates. ² Inhalation doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day. ³ PDR in mg/day is converted to an exposure concentration mg/m ³ using this formula: $mg/m^3 = (mg/day) / (8\ hrs/day \times 1.25\ m^3/hr)$. The breathing rate used in the exposure assessment for humans is 1.25 m ³ /hour S ⁴ Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc. ⁵ Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the Industrial Hygienist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE; LOAEL-based fold factor = 1000/MOE.							

- **General Population Calculations:**

- Risks were not identified for the general population for systemic effects via oral exposures based on quantitative hazard data for a component of the new chemical (MOE > 1,000 for adults and susceptible subpopulations; benchmark MOE = 100).

Focus General Population and Consumer MOE Calculations									
MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Benchmark (acceptable) MOE ≥100									
Exposure Scenarios and Values ¹	POD= NOAEL (mg/kg/day)	POD Route Absorp Adj ²			Exposure Acute Dose Rate (mg/kg/day)	Exposure Route Absorp Adj ²	for Sensitive Sub-populations ⁴	Structural Alert/ Component as % of PMN	Margin of Exposure (POD/PMN Dose)
GENERAL POPULATION RISK									(NOAEL=100)
<i>Highest/Worst Case Doses from Exposure Report</i>									(LOAEL=1000)
Drinking Water	(
DW - Infants	(
¹ General Population and Consumer ingestion Acute Dose Rates are from the Exposure Report and are generated using E-FAST which assumes a 100% absorption rate, and uses an average adult body weight of 80 kg. Consumer ADRs are generated using the Consumer Exposure Module within the E-FAST CBI version called "NCEM2" model. ² Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc. ³ Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment. ⁴ Multiplier based on increased drinking water consumption for infants. Multiplier would be less for older populations, so this value is worst-case.									

- Risks were not quantified for the general population for systemic effects via inhalation since exposure was below the modeling threshold.

- **Consumer Calculations:**

- Risks were not quantified for consumers since consumer use is not expected.